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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,476	01/18/2001	Irina A. Buhimschi	BUH385-00/01003A	9887
7590	05/05/2004		EXAMINER	
Thomas E. Sisson Jackson Walker LLP 112 E pccan street Suite 2100 San Antonio, TX 78202			SNEDDEN, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1653	
			DATE MAILED: 05/05/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/765,476	BUHIMSCHI ET AL.
	Examiner	Art Unit
	Sheridan K Snedden	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 and 20-22 is/are pending in the application.
 - 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) Claim(s) 22 is/are allowed.
- 6) Claim(s) 1,3,5-10,12-18,20 and 21 is/are rejected.
- 7) Claim(s) 1-18 and 20-21 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 4 February 2004. Claim 19 was previously canceled. Applicant's amendment of claims 1, 6, 7, 8, 10, 11, 12, 20, 21, and 22 is acknowledged. Claims 1-18 and 20-22 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, 7-9, 12-14, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Coutsoudis *et al.* (AIDS. 1999 Aug 20;13412):1517-24). Coutsoudis *et al.* teach that the provitamin A, or Beta-carotene, supplementation has the potential for reducing the incidence of preterm births. The supplementation was given to women likely to suffer from preterm labor. Claim 1 has been amended to identify the patient population as a pregnant animal experiencing excess free radical generation. Whereas this amendment specifies a particular patient population, there is no teaching in the specification as how to identify such a patient.

Furthermore, patients at risk of premature labor would have resulted from their exposure to excess free radical generation. Thus, the reference clearly anticipates the invention as recited in the claims.

Applicant argues that Coutsoudis *et al.* teaches that provitamin A or Beta-carotene supplementation to improve the overall health of a population of women, which results in the decrease preterm delivery rate. Applicant's argue that the teaching cannot be generalized to the general population and that the teachings applies to a very select population of HIV infected women. Furthermore, Applicant argues that the teachings of Coutsoudis *et al.* are not confirmed by others. Applicant further argues inoperability at page 9 of the response.

These arguments filed have been fully considered but they are not persuasive. The claims do not exclude any one population, as such, any specific population would read on the claims. Furthermore, the claims are directed to an improved method of preventing the occurrence of preterm labor, however, the method comprises the single step of administering a free radical scavenger. This step is taught by Coutsoudis *et al.* Evidence that the result is poor is not persuasive, as the Coutsoudis *et al.* would be prior art for all that is teaches, and that is the administration of a free radical scavenger that resulted in the reduced occurrence of preterm labor. The exact mechanism is not relevant to the reading of the claims. Because vitamin A supplementation is not outside the scope of the claims, the invention is taught by Coutsoudis *et al.*

5. Claims 1, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrett *et al.* (Int J Vitnm Nutr Res. 1994;64(3):192-7). Barrett et al. teach the potential role

of the antioxidants ascorbic acid (vitamin C) and beta-carotene in the prevention of preterm rupture of fetal membranes. Claim 1 has been amended to identify the patient population as a pregnant animal experiencing excess free radical generation. Whereas this amendment specifies a particular patient population, there is no teaching in the specification as how to identify such a patient. Furthermore, patients at risk of rupture of fetal membranes would have resulted from their exposure to excess free radical generation. Thus, the reference clearly anticipates the invention as recited in the claims.

Applicant argues upon specifics of the scientific method used by Barrett et al. that has no bearing on the language of the claim. Applicant argue that the findings are representative of African black females and that the teachings are inoperable. These arguments filed have been fully considered but they are not persuasive. The claims do not exclude any population and read upon the Barrett *et al.* teaching that antioxidants may reduce the occurrence PPOM.

Furthermore, the claims are directed to an improved therapy but fail to point out what element constitutes an improvement. As such, no distinction can be made between the prior art and current claims.

6. Claims 1, 3, 5, 7-9, 12-14, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese patent 60/197669. Japanese patent 60/197669 teaches the use of a substance that contains tocopherol (vitamin E), an antioxidant, effective for the remedy of premature labor. Claim 1 has been amended to identify the patient population as a pregnant animal experiencing excess free radical generation. Whereas this amendment specifies a particular patient population,

there is no teaching in the specification as how to identify such a patient. Furthermore, patients at risk of premature labor would have resulted from their exposure to excess free radical generation. Thus, the reference clearly anticipates the invention as recited in the claims.

Applicant argues that a teaching of the potential use for vitamin E as a substance to prevent preterm labor does not read upon a method comprising the step of administering vitamin E. This argument is unpersuasive as use of vitamin E for treatment would inherently include the step of administration.

Furthermore, the claims are directed to an improved therapy but fail to point out what element constitutes an improvement. As such, no distinction can be made between the prior art and current claims.

New Rejections

Claim Objections

7. Claims 2, 4, 10, 11 are objected to because of the following informalities:

Claim 4 is objected to for the use of “NAC.” Please note that for clarity, “NAC” should be spelled out in full at first use in an independent or dependent claim.

Claim 10 is objected to because “inhabit” at line 4 of claim 10 should read “inhibit”.

Claim 11 is objected to because “catalse” at line 4 of claim 10 should read “catalase”.

Claims 2, 4, and 11 are objected for dependency on rejected claims. Appropriate correction is required.

Claims 1-18 and 20-21 are objected to because the claim recites an improve method but does not follow the proper form to be used for such Jepson claims. See 37 CFR 1.75(e), which states:

Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:

- (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known,
- (2) A phrase such as "wherein the improvement comprises," and
- (3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 recite an endpoint of "improve outcome of premature labor" where the precise meaning is unclear. From the ordinary meaning of the words, one day before the due date of delivery would read upon the term premature. This differs from certain medical usage of the term that may have a more precise meaning. However, this precise meaning is absent the specification and thus, the scope of the invention is indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6, 10, 20, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Yallampalli *et al.* (US Patent 5,910,482). Yallampalli *et al.* teach the administration of CGRP with the addition a salicylate (spin trapping compound) for treatment to prevent preterm labor. Furthermore, the claims are directed to an improved therapy but fail to point out what element constitutes an improvement. As such, no distinction can be made between the prior art and current claims. Thus, the reference clearly anticipates the invention as recited in the claims.

Conclusion

10. Claim 22 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
May 3, 2004

SKS

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600